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# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No. : 10/797,303 Confirmation No. 4452

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Art Unit : 3734

Examiner : Diane D. Yabut

Title : DEVICES AND METHODS FOR PLACEMENT OF

PARTITIONS WITHIN A HOLLOW BODY ORGAN

Docket No.: : SATTY 69240

Customer No. : 24201

Date : February 20, 2008

# <u>RESPONSE</u>

#### Dear Sir:

This paper is responsive to the Office action mailed November 21, 2007, the response for which is due February 21, 2007. Reconsideration is respectfully requested.

Claims start on page 2.

Remarks start on page 6.

## **AMENDMENTS TO THE CLAIMS:**

The listing of claims will replace all prior versions, and listings, of claims in the application:

#### **LISTING OF CLAIMS:**

1. (Previously Presented) A gastroplasty device, comprising:

a first acquisition member and a second acquisition member in apposition to one another along a first longitudinal axis, wherein at least one of the acquisition members is adapted to adhere tissue thereto such that the tissue is positioned between the first and second acquisition members, and at least one of the acquisition members is movable relative to the first longitudinal axis between a delivery configuration and a deployment configuration.

## 2. (Canceled)

- 3. (Currently Amended) The device of claim 1 further comprising an elongate body attachable to the <u>first and second</u> acquisition <u>members</u> apparatus.
- 4. (Previously Presented) The device of claim 3 wherein a second longitudinal axis defined by the elongate body is parallel with the first longitudinal axis.
- 5. (Original) The device of claim 1 wherein each of the first and second acquisition members are adapted to adhere tissue thereto.
- 6. (Original) The device of claim 1 further comprising a septum removably positioned between the first and second acquisition members.
- 7. (Previously Presented) A gastroplasty device for forming a gastric pouch, comprising:

a distal working portion having a longitudinal axis, a perimeter and an inner volume, and further having a tissue acquisition member along the longitudinal axis adapted to adhere tissue thereto such that the tissue is positioned within the inner volume and about the perimeter of the distal working portion to define a gastric pouch, and the

tissue acquisition member is movable relative to the longitudinal axis between a delivery configuration and a deployment configuration.

- 8. (Original) The gastroplasty device of claim 7 wherein the distal working portion has a rectangular configuration.
- 9. (Original) The gastroplasty device of claim 7 wherein the distal working portion has a arcuate configuration.
- 10. (Original) The gastroplasty device of claim 7 further comprising an elongate body attachable to the distal working portion.
  - 11. (Original) The gastroplasty device of claim 7 further comprising a septum.
  - 12. (Canceled)
- 13. (Original) The gastroplasty device of claim 7 further comprising an expandable element.
- 14. (Original) The gastroplasty device of claim 13 wherein the expandable element is selected from the group consisting of a scope, a balloon, and a wire form.
- 15. (Original) The gastroplasty device of claim 7 adapted for use with an endoscope.
- 16. (Original) The gastroplasty device of claim 7 further comprising a transducer.
- 17. (Original) The gastroplasty device of claim 11 wherein the tissue acquisition member is pivotally movable relative to the septum.
- 18. (Previously Presented) The gastroplasty device of claim 11 wherein the septum comprises a bioabsorbable material.

- 19. (Previously Presented) The gastroplasty device of claim 18 wherein the bioabsorbable material is selected from the group consisting of polylactic acid (PLA), poly(lactic-co-glycolic acid) (PLGA), and polyglycolic acid (PGA).
- 20. (Original) The gastroplasty device of claim 7 wherein the tissue acquisition member comprises a cartridge assembly containing at least one fastener therein for affixing to tissue.
- 21. (Previously Presented) A gastroplasty device for forming a gastric pouch, comprising:

a distal working portion having a longitudinal axis, a perimeter and an inner volume, and further having a vacuum chamber adapted to adhere tissue thereto such that the tissue is positioned within the inner volume and about the perimeter of the distal working portion to define a gastric pouch, and the vacuum chamber is pivotable relative to the longitudinal axis between a delivery configuration and a deployment configuration.

- 22. (Original) The gastroplasty device of claim 21 further comprising an expandable element.
- 23. (Original) The gastroplasty device of claim 22 wherein the expandable element is selected from the group consisting of a scope, a balloon, and a wire form.
- 24. (Original) The gastroplasty device of claim 21 adapted for use with an endoscope.
- 25. (Original) The gastroplasty device of claim 21 further comprising a transducer.
- 26. (Original) The gastroplasty device of claim 21 further comprising a septum.
- 27. (Previously Presented) The gastroplasty device of claim 26 wherein the septum comprises a bioabsorbable material.

28. (Previously Presented) The gastroplasty device of claim 27 wherein the bioabsorbable material is selected from the group consisting of polylactic acid (PLA), poly(lactic-co-glycolic acid) (PLGA), and polyglycolic acid (PGA).

#### **REMARKS**

Claims 1, 3-11 and 13-28 are pending in the application and have been rejected. Claim 3 has been amended. No new matter has been added. Reconsideration is requested.

Applicant wishes to acknowledge the courtesies extended by Examiner Yabut during the telephonic interview of December 19, 2007. The undersigned has reviewed the substance of the interview set forth in the Examiner's Interview Summary mailed December 27, 2007. The Examiner's Statement, and identification of the art and claims that were discussed is accurate. Further, the undersigned argued that the clamp disclosed in the Schurr reference did not have pivotal movement along the longitudinal axis, rather it has movement that is transverse to the longitudinal axis. Further, the undersigned argued that neither Schurr nor Deem were confronted with a removable septum separating the folds of tissue. It was further argued that Schurr is a clamp or drawbridge that creates only one tissue acquisition member, not two, as recited in the claims of the present invention, and it therefore does not have to deal with the removable septum. Finally, it was argued that a person skilled in the art would not apply the pivoting movement of Schurr to the Deem device, because Deem is not pivotal at all. In other words, a person skilled in the art would substantially reconfigure the Deem advice by adding a pivot point along the longitudinal axis.

Claim 3 was objected to because "the acquisition apparatus" in line 2 does not have sufficient antecedent basis. Claim 3 is amended to now recite "the first and second acquisition members," which does have sufficient antecedent basis.

Claims 1-28 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Deem (U.S. Pat. No. 6,558,400) in view of Schurr (U.S. Pub. No. 20020082621). Applicant respectfully traverses this rejection.

"[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." <u>In re Kahn</u>, 441 F.3d 977,

988 (Fed. Cir. 2006), cited with approval in KSR Int'l Co. v. Teleflex, Inc., 127 S. Ct. 1727(2007). To facilitate review, "this analysis should be made explicit." See Memorandum, May 3, 2007, from Margret A. Focarino, Deputy Commissioner for Patent Operations to Technology Center Directors. A *prima facie* case of obviousness cannot be made absent the proper analysis. In this case, the Examiner provides only a conclusory statement that "it is well known in the art that pivotable tissue acquisition members facilitates grasping and apposition of tissue to ensure a secure engagement of the tissue(s)." No evidence to support this statement is provided by the Examiner. For this reason, the obviousness rejection of claims 1, 3-11 and 13-28 should be withdrawn.

This obviousness rejection should also be withdrawn because not all of the elements of the claims are taught by the combination of Deem and Schurr. Claim 1 recites that "at least one of the acquisition members is movable relative to the first longitudinal axis between a delivery configuration and a deployment configuration." Examiner admits Deem does not disclose this limitation. Examiner also states that "Schurr teaches a tissue acquisition member 200 being pivotally movable relative to a septum 110 (Figures 4-5)." But, Schurr does not disclose a septum; instead Schurr discloses an overtube 110 that is positioned to a desired location. See paragraphs [0057] and [0061] of Schurr. Further, Schurr does not disclose an acquisition member being movable relative to the longitudinal axis of the first and second acquisition members. As shown in FIGS. 4 and 5, the acquisition member 200 of Schurr moves relative to an axis transverse to the longitudinal axis of the acquisition member. Even assuming *arguendo* that Deem is combinable with Schurr, not all of the elements of claims 1 and 3-6 are disclosed, and therefore, these claims are patentable over Deem in view of Schurr.

The device in the Deem reference does not pivot. The Deem device would have to be substantially changed in order to add a longitudinal pivot point as suggested by the Examiner in reviewing the Schurr reference. In other words, a person having ordinary skill in the art would have to substantially modify Deem in view of the transverse pivot point disclosed in Schurr. There is simply no evidence that such a skilled artisan would completely redesign the Deem device based on the transverse pivoting movement of the Schurr device.

Similarly, independent claim 7 recites that "the tissue acquisition member is

movable relative to the longitudinal axis between a delivery configuration and a

deployment configuration." Also, independent claim 21 recites that "the vacuum

chamber is pivotable relative to the longitudinal axis between a delivery configuration

and a deployment configuration." As discussed above, Schurr discloses an acquisition

member 200 that moves relative to an axis transverse to the longitudinal axis of the

acquisition member, and not relative to the longitudinal axis. Accordingly, claims 7-11

and 13-28 also are allowable over Deem in view of Schurr.

Applicant has attempted to respond to each and every rejection set forth in the

Office action. Claims 1, 3-11 and 13-28 remain pending in the application and

reconsideration is respectfully requested. The undersigned can be reached at (310) 824-

5555 to facilitate prosecution of the application.

Respectfully submitted,

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